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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,410	07/08/2003	Tony Hunter	066671-0043	9290

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,410	HUNTER ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-7, 9-11, 20-21, 23-25 and 31-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9-11,20,21,23-25 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/29/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed on 3/2/06 in response to the previous Non-Final Office Action (8/26/05) is acknowledged and has been entered.

Claims 1-5, 8, 12-19, 22, 26-30 have been cancelled. Claims 6-7, 9-11, 20-21, 23-25 have been amended. Claims 31-36 have been added.

Claims 6-7, 9-11, 20-21, 23-25 and 31-36 are pending and under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

The following office action contains NEW GROUNDS of rejection.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 5/29/05 are/is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

Objection/Rejections Withdrawn

1. The Objection of The specification for lacking cross-reference information to parent applications is withdrawn in view of the applicant argument and amendment to the specification.

2. The Objection of Applicant's claiming priority to US application 09/275900 ('900), filed on 03/24/1999, is acknowledged and US application 08/555912 ('912), filed on 11/13/1995 is withdrawn in view of the applicant argument and amendment to the claims.

3. The rejection of Claims 4-30 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of " nucleotide sequence substantially the same" and claims 4 and 18 for "at least about 15 contiguous nucleotides" are is withdrawn in view of the cancellation and amendment to the claims.

4. The rejection of Claims 4-30 under 35 U.S.C. 112, first paragraph, as drawn to new matter, is withdrawn in view of applicant argument and the cancellation and/or amendment to the claims.

5. The rejection of Claims 4-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as drawn to substantially the same as nucleotide or hybridize to 13-129 or

175-489 of SEQ ID NO: 1 and sequence variant encoding a portion of Pin1 polypeptide is withdrawn in view of the cancellation and/or amendment to the claims.

6. The rejections of claims 4-30 under U.S.C. 102(e) as being anticipated by Baker et al., and Claims 18-30 under 35 U.S.C. 102(e) as being anticipated by Mattews et al., are withdrawn in view of the priority given as stated above.

7. The rejection of claim 4 in part under 35 U.S.C. 102(b) based upon a public use or sale of the invention are withdrawn in view of the cancellation to the claim.

The following is a New Ground of rejection

Claim Objections:

Claims 9 and 23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for **failing to further limit the subject matter of a previous claim**. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 is drawn to a nucleotide **comprising** 13-129 of SEQ ID NO: 1 or a portion thereof and Claim 23 is drawn to a nucleotide **comprising** 175-489 of SEQ ID NO: 1 or a portion thereof. In order to be a proper dependent claim, the dependent claim should include all the limitation of its base claim, claim 6, or 20, which is drawn to an isolated nucleotide encoding a domain **consisting of** amino acid 5-43 or 175-489 of SEQ IDNO: 1. The additional sequences of "comprising" in the claims 9 or 23 are not included in the base claims.

Claim Rejections:

Under the second paragraph of 35 U.S.C. 112:

Claims 6-7, 9-11, 20-21, 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 6 is vague and indefinite in the recitation of " an isolated nucleic acid ..... encoding WW domain of a Pin 1 polypeptide consisting of ", and claim 20 is vague and indefinite in the recitation of " an isolated nucleic acid ..... encoding PPIase domain of a Pin 1 polypeptide consisting of ". It is not clear the isolated nucleic acid is the molecule encoding WW or PPIase domain of Pin 1 or the molecule encoding the entire Pin 1 protein. The claims 6 and 20 also render the dependent claims indefinite.

2. Claims 11 and 25 are vague and indefinite in the recitation of "selectively hybridize". When given the broadest reasonable interpretation, "selectively hybridizes" can include larger sequences that minimally comprise residues 13-129 or 175-489 of SEQ ID NO: 1 as well as larger sequence, which minimally comprises a variant sequence of the residues. It is unclear how much deviation from the Watson-Crick base pairing would be encompassed by the claim because the metes and bounds of the term "selectively hybridize" is unclear. For purpose of examination, the claim will be read as comprising a variant sequence.

Under the first paragraph of 35 U.S.C. 112:

As drawn to written description:

Claims 6-7, 9-11, 20-21, 23-25 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case,

(A), the claims are inclusive of a genus of nucleotides fragments comprising 13-129 or 175-489 of SEQ ID NO: 1 and a portion thereof encoding complement thereof (claims 9, 23).

(B), the claims are inclusive of a genus of nucleotides, which can be selectively hybridized to 13-129 or 175-489 of SEQ ID NO: 1.

(C), the claims are inclusive a genus of nucleic acid molecule encoding a fragment SEQ ID NO: 2 comprising domain WW domain of amino acid 5-43, PPIase domain of amino acid 59-163, or functional fragment thereof.

However, the specification only sets forth a nucleotide, SEQ IDNO: 1, encoding Pin (SEQ ID NO: 2) and nucleotides sequence of 13-129 of SEQ I D NO: 1 encoding WW at amino acids residues 5-43 of SEQ IND NO: 2 and 175-489 of SEQ ID NO: 1 encoding PPIase domains at amino acid residues 59-163 of SEQ ID NO: 2, which has NIMA binding activity or PPIase activity separately. The specification does not provide the condition for selective hybridization. The instant claims encompass signification structural dissimilarity as compared to the SEQ ID NO: 1 or the nucleotide encoding Pin1, SEQ ID NO: 2, and its domains. The nucleotide of 13-129 or 175-489 of SEQ ID NO: 1 does not anticipate the claimed genus because the genus includes molecules, which differ widely both in functional attributes and structural attributes from the nucleotides disclosed in the written description.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is partial structures in the form of a recitation of a nucleotide sequence substantially the same as nucleotide 13-129 or 175-489 of SEQ ID NO: 1, which have the NIMA binding activity (protein-protein interaction) and PPIase activity. There is no identification of any particular portion of the structure that must be conserved except nucleotide 13-129 or 175-489 of SEQ ID NO: 1, or a nucleotide sequence encoding a portion of polypeptide of 5-43 or 59-163 of SEQ ID NO: 2 to have such function or activity. The instant specification does not set forth that particular sequence variants encoding any particular portion of the amino acid sequence of SEQ ID NO: 2 has protein-protein interaction or PPIase activity except a nucleotide sequence encoding a polypeptide of 5-43 or 59-163 of SEQ ID NO: 2.

Protein chemistry is probably one of the most unpredictable areas of biotechnology. It is well known in the art that proteins are folded 3-dimensional structures, the function and stability of which are directly related to a specific conformation (Mathews and Van Holde, Biochemistry, 1996, pp. 165-171). In any given protein, amino acids distant from one another in the primary sequence may be closely located in the folded, 3-dimensional structure (Mathews and Van Holde, Biochemistry, 1996, pp. 166, figure 6.1). It is also known in the art that even a single modification or substitution in a protein sequence can alter the protein function including ability of protein-protein interaction. For example, the replacement of a single lysine at position 118 of the acidic fibroblast growth factor by aglutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (Burgess et al, Journal of Cell biology, Vol 111, p2129-2138, 1990).

The instant specification does not provide a specific functional characteristic of a nucleotide sequence substantially the same as nucleotide 13-129 or 175-489 of SEQ ID NO: 1. The instant specification does not provide a specific functional characteristics of the nucleotide sequence or nucleotide sequence variant encoding a portion of polypeptide having substantially the same sequence as amino acid 5-43 or 59-163 of SEQ ID NO: 2. Accordingly, in the absence of sufficient recitation of distinguishing structural and functional characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acid consisting of nucleotide sequence 13-129 and 175-489 of SEQ ID NO: 1, which encode an amino acid 5-43 or 59-163 of SEQ ID NO: 2, but not the full breadth of

the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

As drawn to enablement: host cell

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **an isolated host cell** in vitro, does not reasonably provide enablement for a host cell in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification states on paragraph 83 (PG pub) that various viral vectors, which can be utilized for gene therapy as taught herein include adenovirus, herpes virus, vaccine, or, preferably, an RNA virus such as a retrovirus. Preferably, the retroviral vector is a derivative of a murine or avian retrovirus. The specification on paragraph 42 also states that hosts can include microbial, yeast, insect and mammalian organisms. Biologically functional viral and plasmid DNA vectors capable of expression

and replication in a host are known in the art. Such vectors are used to incorporate DNA sequences of the invention.

The instant specification does not teach how to overcome problems with in vivo delivery and expression with respect to the administration of the claimed nucleic acids or viral vectors comprising said nucleic acids. The state of the art as of the priority date sought for the instant application is that in vivo gene delivery is not well developed and is highly unpredictable. For instance Verma et al., (Nature, 1997, Vol. 389, pp. 239-242) teach that the Achilles heel of gene therapy is gene delivery. Verma et al state that the ongoing problem is the inability to deliver genes efficiently and to obtain sustained expression (page 239, column 3). Eck et al., (Gene-Based Therapy, In: The Pharmacological Basis of Therapeutics, Goodman and Gilman, Ed.s, 1996, pp. 77-101) teach that the fate of the DNA vector itself with regard to the volume of distribution, rate of clearance into tissues etc., the in vivo consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA the level of mRNA produced, the stability of the mRNA produced in vivo, the amount and stability of the protein produced and the proteins compartmentalization or secretary fate within the cell are primary considerations regarding effective therapy. Eck et al., state that these factors differ dramatically on the vector used, the protein being produced, and the disease being treated (Eck et al., bridging pages 81-82).

As of the priority date sought, it was well known in the art how to infect or transfect cells in vitro or ex vivo with viral vectors. However, using viral vectors to deliver DNA to an organism in vivo, or using infected or transfected cells to deliver nucleic acids which encode a particular protein sequence to an organism in vivo is in the realm of gene therapy, and as of the priority date sought, highly unpredictable in view of the complexity of in vivo systems. Orkin et al., state ("Report and Recommendation of the Panel to Assess the NIH Investment in Research on Gene Therapy", NIH, 1995) that as of 1995, clinical efficacy had not been definitively demonstrated with any gene therapy protocol (page 1, second paragraph). Orkin et al., defines gene therapy as the transfer of DNA into recipient cells either ex vivo or in vivo (page 7, under the heading "Gene transfer"), thus encompassing the instant claims drawn to the administration of antigen presenting cells transfected or infected ex vivo. Orkin et al., concludes that, "none of the

available vector systems is entirely satisfactory, and many of the perceived advantages of vector systems have not been experimentally validated. Until progress is made in thee areas, slow and erratic success in applying gene transfer methods to patients can be expected" Orkin et al., comment that direct administration of DNA or DNA in liposomes is not well developed and hindered by the low efficiency of gene transfer (page 8, paragraph 5). Orkin et al., teach that adequate expression of the transferred genes is essential for therapy, but that current data regarding the level and consistency of expression of transferred genes in animal models was unknown. Orkin et al states that in protocols not involving ex vivo infections/transfection, it is necessary to target the expression of the transferred genes to the appropriate tissue or cell type by means of regulatory sequences in gene transfer vectors. The specification does not teach a vector having a specific regulatory sequence, which would direct the expression of the nucleic acids within the appropriate tissue type.

The specification does not remedy any of the deficiencies or the prior art with regard to gene therapy. Given the lack of any guidance from the specification on any of the above issues pointed out by Verma or Eck or Orkin et al. One of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to practice the methods of claims. ***Applicants is informed that amending the claim to " an isolated host cell comprising ...." Would overcome the rejection.***

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31, 32 and 35-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 5972697 ('697). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-4 of U.S. Patent '697 anticipate the instant claims 31-32 and 35-36.

Claim 31 is drawn to an isolated DNA encoding a fragment of Pin 1 consisting of amino acid 1-163 of SEQ ID NO: 2 (full length of Pin 1 protein), wherein the encoded fragment **comprise** amino acid residues 5-43 of SEQ ID NO: 2 and binds to NIMA. Claim 32 is drawn to an isolated DNA encoding a fragment of Pin 1 consisting of amino acid 1-163 of SEQ ID NO: 2 (full length of Pin 1 protein), wherein the encoded fragment comprised amino acid residues 59-163 of SEQ ID NO: 2 and has PPIase activity. **Thus, the** nucleotide encoding a fragment **comprising residues 5-43 or 59-163 of SEQ ID NO: 2** in both claims read on an nucleotide **encoding a full length of Pin 1 (SEQ ID NO: 2).** Claims 35-36 are drawn to a vector and host comprising the nucleotides of claims 31-32.

Claims 1-2 of U.S. Patent No. '697 teach an isolated nucleic acid sequence encoding Pin1 protein having SEQ ID NO: 2 or variation thereof which encode the same amino acid sequence. Claims 3-4 of '697 teach a vector and host comprising the nucleotides in claim 1-2.

It would have been prima facie obvious at the time the claimed invention was made to make a nucleotides encoding a full length of Pin 1, which would comprise residues 5-43 or 59-163 of SEQ ID NO: 2. One of ordinary skill in the art would have been motivated with reasonable expectation of success to make the nucleotides comprising a nucleotides encoding a full length Pin1 protein (1-163 amino acid of SEQ ID NO: 2) as claimed in the Patent '697. Because both sets of claim are directed to the same isolated DNA, because the instant claims encompass an isolated nucleotides encoding a protein comprising 5-43 or 59-163 of SEQ ID NO: 2, which include a nucleotide encoding a full Pin 1 protein, the claimed invention is obviousness over the claims 1-4 of U.S. Patent No. '697.

Conclusion

NO claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

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Karen A. Canella
KAREN A. CANELLA PH.D
PRIMARY EXAMINER